AUDIOMETER SIBELMED AS5

USER MANUAL

520-500-MU2 • Rev 2.02 • 2013-06

CONTENTS

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PRODUCTO CONFORME
93/42/CEE Directiva de Productos Sanitarios.
Clase II a

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SAFETY

SPECIAL PRECAUTIONS

The AS-5 audiometer has been designed to have the maximum safety.

All the operation instructions should be read before starting the device. Otherwise, lesions to the user or patient and damage to the device and/or accessories may happen.

INTENDED USE

The audiometer generates a series of acoustic and vibrational stimuli and calculates a series of parameters relating to human audiometry.

The audiometer is intended for use by medical staff only, under the supervision and instruction of a doctor.

The audiometer is not intended for use outdoors, nor in conditions or with energy sources other than as set out in this manual.

DO **NOT** use transducers (headphones for air/bone conduction, loudspeakers, ...) that have not been calibrated with the audiometer. **THAT COULD INVALIDATE THE AUDIOMETRIC TEST PERFORMED.**

THE ROLE OF THE PATIENT IN THE USE OF THE AUDIOMETER

The audiometry tests require the cooperation of the patient. The patient must press a button to communicate the detection of a stimulus. The doctor must evaluate the patient's ability to carry out the audiometry tests. Special care must be taken with children, the elderly and the handicapped.

LIMITATIONS OF USE. CONTRAINDICATIONS

The interpretation of the tests and the derived treatments should

be performed by a doctor.

The medical staff must evaluate any symptoms presented by the patient before any audiometric tests are carried out.
The suitability of audiometric testing is the responsibility of the medical staff.

The audiometer should not be used when it is likely that the validity of the results could be compromised by external factors.

Take care NOT to place the equipment where it could be splashed
by water or other liquids or cover it with objects that prevent air from circulating around it while it is running.
The device should NOT be used stacked or adjacent to other equipment.

All accessories and spare parts, etc. must be originals and are to be requested from the manufacturer or authorized distributor in order to ensure the safety of the patient and the correct working order of the spirometer and the safety of the patient. Thus, this may increase the emissions or decrease its immunity.

The equipment must be stored and used within the temperature, pressure and humidity ranges specified in this manual.

ELECTRICAL RISKS

DO NOT remove the device or accessories cover. Servicing and repair of
the apparatus must only be carried out by trained personnel.
Contact with the voltage inside the system can cause serious injury.

DO NOT use the equipment if the power cable is in poor condition or cracked.

DO NOT use damaged accessories

NEVER immerse any part of the equipment in liquid. **THIS COULD CAUSE AN ELECTRICAL DISCHARGE.**

To ensure vital safety features under the EN 60601.1 standard, only equipment compliant with the electrical safety standards in force may be connected to this device. To connect AS-5 to a non-medical device with ground conductor, you must install an additional ground conductor to the non medical device.

DO NOT use multiple mains sockets, unless they comply with EN-60601-1. They can degrade electrical safety.

RISK OF EXPLOSION

DO NOT use this equipment in the presence of anaesthetics or flammable gases. **THIS COULD CAUSE AN EXPLOSION.**

INTERFERENCE RISK

This is an electronic product, so high frequency emissions can interfere with the correct use. For this reason, the products which can generate interferences (radios, cellular phones, etc.) should be kept apart.

The portable or mobile radiofrequency devices can affect the normal functioning of the electronic medical devices.

This is a medical electronic device and as such it needs special precautions regarding the electromagnetic compatibility (EMC) and it should be installed and setup according to the EMC information attached (See **Appendix 1. ELECTROMAGNETIC COMPATIBILITY**).

The use of transducers, accessories and cables different to the ones specified here, except the transducers and cables sold by the manufacturer as spare parts, could adversely affect patient safety, cause a malfunction of the equipment and/or produce an increase of the emissions or a decrease in the device immunity.

DISPOSAL OF ELECTRICAL OR ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

This symbol on the product indicates that it must not be disposed of as part of domestic waste.

Rather, if it is to be disposed of, it is the user's responsibility to take it to a designated recycling point for electrical and electronic devices. The separate collection and recycling of different kinds of waste at the point of disposal helps to preserve natural resources and to ensure that recycling will safeguard health and the environment. If you require further information about where to take products of this type for recycling, contact your local authority, the local domestic waste disposal service or the distributor from whom you purchased the product.

1. OPERATING INSTRUCTIONS

1.1. INTRODUCTION

The SIBELMED AS5 audiometer is a compact unit based on a tone generator, a white noise generator (optional), a set of air conduction earphones, a bone conduction vibrator (optional), and a liquid crystal alphanumerical screen. The whole system is controlled by a microprocessor that provides a reliable, quick and simple way to carry out an audiometry.

The SIBELMED AS5 audiometer has been entirely developed in Spain. The most advanced technology used in other medical instruments, as well as the experience acquired from making audiometers for more than ten years, has been applied to this audiometer.Its functional line and the fact of having eliminated many of the electromechanical components the majority of audiometers currently have, makes of the SIBELMED AS5 audiometer a lasting working instrument.

The SIBELMED AS5 audiometer has been developed following standard criteria from the National Institutions (U.N.E.) as well as from the Internatinal Institutions (I.E.C., etc.)

1.2. PRELIMINARY OBSERVATIONS

Use this manual is intended for all models and options that can make up the audiometer AS-5 Therefore, in each case shall apply only those options or model functions that are available.

This audiometer is built with professional components solid state under strict quality controls. However, accidents can happen in the transportation or storage of equipment so it is advisable to make an initial review of their status prior to installation, as well as accessories to complement it.

WARNING
IF ANY DAMAGE DETECTED IN THE PACKAGE, IMMEDIATELY CONTACT THE AGENCY OF TRANSPORTATION AND YOUR DEALER PRIOR TO INSTALL. DO NOT PULL.

Do not pull any packaging, bag, etc.. until it is fully verified both as running accessories.

1.3. AS-5 AUDIOMETER MODELS

The set of SIBELMED AS5 audiometers is available in four versions with the following differences
between them:

AS5-AOM	With air conduction, bone conduction and masking noise
AS5-AO	Without masking noise
AS5-AM	Without bone conduction
AS5-A	Without masking noise and bone conduction

The table below shows each model's built-in features as standard (Shadedo) and other items which can be included as optional (White). You can upgrade to a higher model by adding the relevant features at any time. All you need to do is contact the SIBEL S.A. Sales Department or your distributor.

RELACIÓN DE CONTENIDO / PACKING LIST

Página 1 de 1

AUDIOMETRO AS5 / AS5 AUDIOMETER

520-500-010 REV. 4.00
2012-04

MODELOS / *MODELS*

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	AM	AO	AOM
—	1	AUDIOMETRO SIBELMED AS5 / *AS5 AUDIOMETER* Nº: 205-				
01807	1	CONEXION AVISO PACIENTE / *PATIENT SWITCH*				
02260	1	JUEGO AURICULARES VIA AEREA / *EARPHONE SET*				
—	1	MANUAL DE USO AS-5 (Doc. 520-500-MU1) *AS-5 USER´S MANUAL (Doc. 520-500-MU2)*				
02180	100	GRAFICA AUDIOMETRICA / *AUDIOMETRIC GRAPHIC PAPER*				
07482	1	BOLIGRAFO ROJO / *RED PEN*				
07483	1	BOLIGRAFO AZUL / *BLUE PEN*				
01217	1	CABLE-CONEXION RED 2m / *MAINS PLUG CABLE 2m*				
02268	1	VIBRADOR VIA OSEA COMPLETO / *BONE VIBRATOR SET*				
02214	1	INTERCONEXION AUDIOMETRO-CABINA *AUDIOMETER - TEST BOOTH CONNECTION*				
01606	1	BOLSA TRANSPORTE / *CARRING BAG*				

STANDARD   ☐ OPCIONAL / *OPTIONAL*   — NO DISPONIBLE / *NOT AVAILABLE*

NOTA:
- [illegible]
- [illegible]
- [illegible]
- [illegible]

NOTE:
- [illegible]
- [illegible]
- [illegible]
- [illegible]

PREPARADO/PREPARED BY.................................   FECHA/DATE: / /

MANUFACTURER'S RESPONSIBILITIES

SIBEL S.A. guarantees the safety, reliability and proper functioning of this equipment provided that:

• The location where the equipment is installed complies with the UNE (IEC) requirements for electrical installations, with an earth connection, and such other standards as may apply.

• Repairs, maintenance and modifications, whether within the warranty period or otherwise, are carried out by SIBEL S.A. technical staff.

• The equipment is used by qualified staff and in accordance with the recommendations in this Instruction Manual.

WARNING

In accordance with the various standards, we recommend testing and calibrating the electromedical equipment periodically in order to guarantee reliable operation of the functions and patient, user and environmental safety.

In addition to the necessary routine maintenance of the AS-5 audiometer, we recommend calibrating the transducers and performing a general check of the safety systems, adjustments, functions, etc. at least once every twelve months (ISO 8253-1).

This should also be done whenever there is reason to suspect that the equipment is malfunctioning.

These checks should be carried out by the maufacturer or by qualified technical staff authorised by SIBEL S.A., in accordance with the manufacturer's (SIBEL S.A.) Procedures for Verification and Adjustment.

1.4. CONTROLS, INDICATORS AND CONNECTORS

1.4.1. GENERAL AND LATERAL PANEL. Fig. 1.3.1.

Nº 1 "0" - "I"
General switch OFF (0) / ON (I)
Nº 2
Block of audiometric graphs for noting down sound pressure levels as well as patient's name, address, etc.

Nº 3 "ENMASC./MASK" ▲
Key for increasing the dB level of the masking noise.

Nº 4 "ENMASC./MASK" ▼
Key for decreasing the dB level of the masking noise.

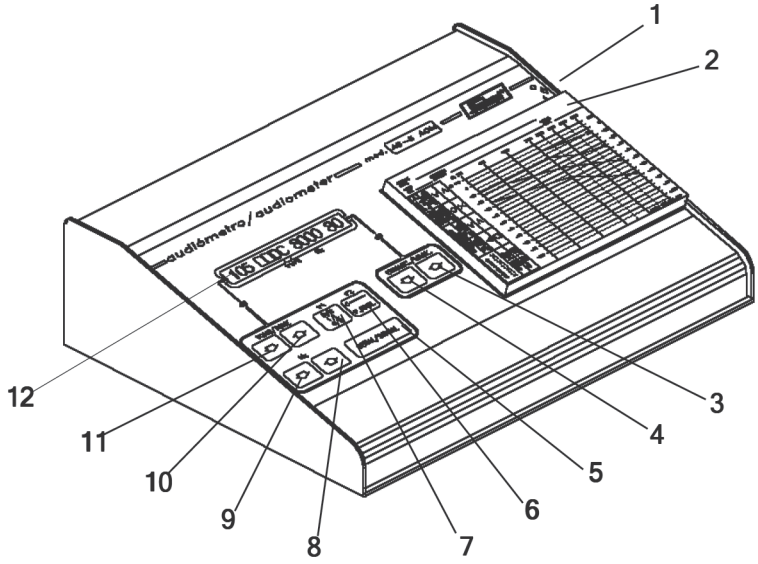


Fig. 1.3.1.

Nº 5 "SEÑAL-SIGNAL"
On being pressed down, this key sends the tone signal to the patient's earphones or bone vibrator.

Nº 6 "F2"
Function key for selecting the form of applying the tone to the patient
"C" = Continuous Tone
"P" = Pulse Tone
The corresponding letter is displayed on the LCD screen, above F2.

Nº 7 "F1"
Function key for selecting the way of applying the tone to the patient.
"D/R" = Derecha / Right. The screen displays "R"
"I/L" = Izquierda / Left. The screen displays "L"
"O/B" = Osea / Bone. The screen displays "B"
The corresponding letter is displayed on the screen, above 1 function.

Nº 8 "Hz" ▲
Key for increasing the frequency applied to the patient.

Nº 9: "Hz" ▼
Key for decreasing the frequency applied to the patient.

Nº 10: "TONO/TONE" ▲
Key for increasing the pure tone level (dB) applied to the patient.

Nº 11: "TONO/TONE" ▼
Key for decreasing the pure tone level (dB) applied to the patient.
Nº 12
LCD alphanumerical screen of 16 x 1. Fig. 1.3.2.

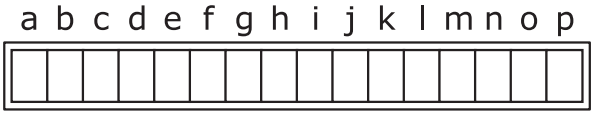


fig. 1.3.2.

- abc dB level corresponding to pure tone
- d Free
- ef Indicates that the pure tone is applied to the patient.
- g Corresponds to F1. R = Right, L = Left and B = Bone
- h Corresponds to F2. C = Continuous and P = Pulse
- i Free
- jklm Frequency selected in Hz
- n Free
- op dB level corresponding to masking noise

1.4.2. REAR PANEL. Fig. 1.3.3.

Nº 13: "I/L" (Blue)
Base for the connection of the left earphone of air conduction

Nº 14: "D/R" (Red)
Base for the connection of the right earphone of air conduction

Nº 15: "0/B" (Yellow)
Base for the connection of the bone vibrator

Nº 16: "PAC /PAT" (White)
Base for the connection of the patient's response push-button

Nº 17:
Features plate

Nº 18
General fuse-holders with slow fuses of 5x20 0.2 A

Nº 19
Base for the connection of power and ground cable

Nº 20
Base for the connection of the additional protection

Nº 21

Set of air conduction earphones

Nº 22
Vibrator for bone conduction

Nº 23
Patient's response connection

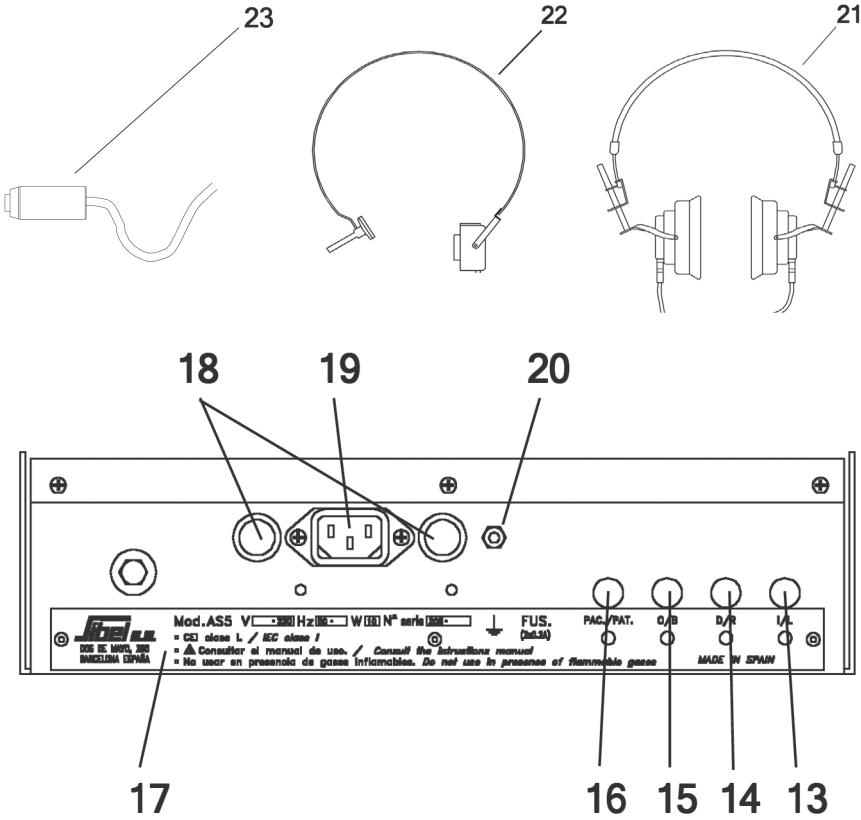


Fig. 1.3.3.

1.5. INSTALLATION AND START-UP

This handbook is applicable to the SIBELMED AS5-AOM audiometer. For AS5-A, AS5-AM and AS5- A0 models will applicable the same, except the sections of this handbook which do not correspond.

In accordance with the type of protection against electrical discharges established in standard EN – 60601-1), the AS-5 audiometer is categorised as CLASS I equipment.

In order to be brought into operation, the SIBELMED AS5 audiometer requires a 220 V 50Hz network wire (other options on request) together with its corresponding earth terminal.

The required ambient conditions are:
- Storage temperature -5 to 70 °C
- Ambient temperature between 5 and 40 °C.
- Relative humidity less than 85% (no condensation).

Be careful of keeping the unit away from sprinkling water or any other liquid. Also do not cover this unit with any object that may prevent proper ventilation while operating.

It is advisable to install the audiometer within a soundproof room for audiometric tests. If this is not possible, the unit should be installed in so quiet a room that test results get not distorted.

The operations order to get the audiometer ready to work is as follows:

1. Turn general switch Nº 1 to "0" (OFF) position

2. Plug power connection in base Nº 19 and in its electric supply of 220V 50Hz (other options on request).

3. Connect air conduction earphones, bone conduction vibrator and patient's response connection to their corresponding bases Nº 13, 14, 15 and 16 in accordance with the colours code described in section 1.3.2.

4. Drive switch Nº 1 to "I" (ON) position. It will light up and fig.

1.4.1. will be displayed on the screen.

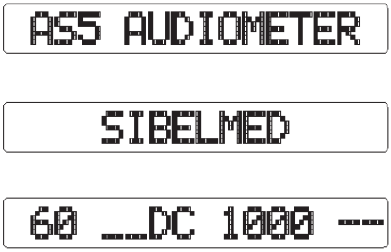


Fig. 1.4.1.

Make sure that when pressing "SEÑAL /SIGNAL" Nº 5 key you can hear the tone on the right earphone.

5. Set the block of audiometric graphs in the place intended for them, Nº 2.

1.6. AUDIOMETRIC TESTS

In this handbook, the mechanics to carry out some basic audiometric explorations are explained. These mechanics can be adapted to those criterions the specialist think more suitable.

Apart from these tests, there exist other tests or variations of them which are not included here. The procedures for these cases will be determined by the specialist. It is advisable for those who are not very acquainted with these techniques to consult publications in the matter.

WARNING:
TRANSDUCER CALIBRATION BEWARE IN OWN TEAM, IF USING A NO TRANSDUCER CALIBRATION, TESTING, DO NOT BE THAT AUDIOMETRIC VALID.
VA TRANSDUCER EACH LABEL WITH AUDIOMETER SERIAL NUMBER HAS BEEN WITH CALIBRATION. MATCHING CHECK BEFORE USING THE TRANSDUCER (HEADSET, Vibrator, ...).

1.6.1. PROCEDURE FOR DETERMINATION OF HEARING THRESHOLD LEVELS THROUGH AIR CONDUCTION WITHOUT MASKING NOISE

The SIBELMED AS5 audiometer has the following frequencies and tone levels for air conduction.

Hz	250	500	1000	2000	3000	4000	6000	8000
Max. dB HTL	90	105	105	105	105	105	90	80
Mín. dB HTL	-10	-10	-10	-10	-10	-10	-10	-10

The place where the audiometry is going to be carried out has to be quiet. It must not disturb the reception of minimum intensity tones generated by the audiometer.

It is absolutly necessary for the patient to be calm, confortably sat and rested, so that he can pay maximum attention to the test. It is also advisable for the patient not to see the operator handling the audiometer during the examination.

The aim of this test is to determine the minimum hearing levels the patient can listen to: hearing threshold level (HTL). The test is carried out by applying pure tones to each ear. Hearing threshold determination can be carried out by testing all the tones with one ear and then with the other, or else, testing successively each tone with one ear and then with the other.

For threshold determination you can proceed according the following steps or similar ones, always in accordance with the specialist's criterions.

1. Explain the patient what the examination is about and tell him/her to press the response connection every time he/she hears the tone, and to keep it pressed down as long as he/she hears it.

Next, put the air conduction earphones on the patient's head according to the following instructions:
"Right ear" = Red; "left ear" = Blue. Make sure the masking noise is not being applied. The digits corresponding to the masking noise level should be displayed along with two dashes (—). This

warns you that this signal is disconnected. Fig. 1.5.1.

Fig. 1.5.1.

2. Examine the ear the patient considers to be the best and start examination with 1000 Hz frequency and then 2000, 4000, 8000, 500 and 250 Hz. Frequencies of 3000 and 6000 Hz are optional.

3. In order to determine the hearing threshold level of each frequency, press "SEÑAL/SIGNAL" key for one, two or three seconds, sending a sufficiently high level, 60 dB for example, so that the patient can distinctively identify it.

At the same time, the two digits on the screen corresponding to the pure tone signal application will light up.

Then, the patient should press the response push-button and the dB value of the tone signal being applied will flash on the screen Fig. 1.5.2.

Fig.1.5.2.

If the patient presses the push-button when the operator is not pressing down the "SEÑAL/SIGNAL" Nº 5 key, Fig. 1.5.3. is displayed on the screen for an instant.

Fig.1.5.3.

4. When a well-defined reply is obtained, progressively diminish the tone level through key Nº 11 in 10 dB jumps, once you have cancelled the pure tone signal (key No 5 without being pressed). When you reach the level at which the patient is uncertain about his reply, go down 10dB further and initiate the ascent throught key Nº 10 in 5dB jumps until the patient answers again. Then, go down again in 5dB jumps until the patient cannot hear anything.

5. Usually, dB level identified by the patient 100% of the times is taken as hearing threshold level.

Fig. 1.5.4.

IMPORTANT:
On noting down the levels on the graph take into account that negative decibels in the graph mean loss of audibility. Therefore, if the patient is applied 10 dB (screen), write - 10dB on the graph, and coversely.

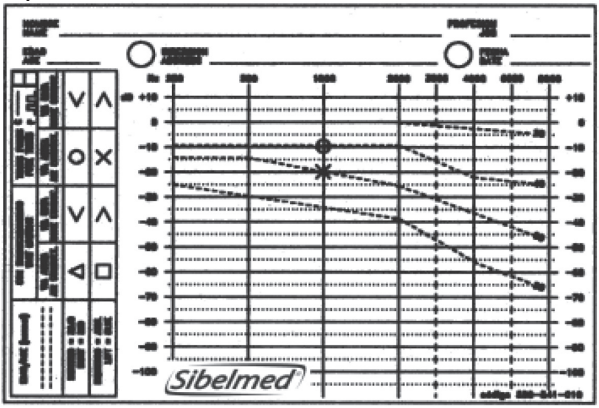


Fig.1.5.4.

6. As hearing thresholds are being found they should be noted down according to the normalized notation and colours code, as the graph shows. Finally, they should be joined together by a line for each ear. Fig. 1.5.5.

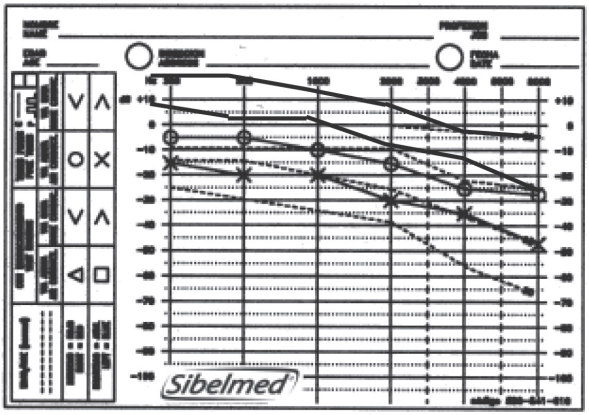


Fig.1.5.5.

7. In those cases you think hearing is normal either in one or both ears, carry out the test in all frequencies at a tone level of 10dB. This will determine in short while whether hearing is normal or not.

8. In some cases, and this is left to the specialist's criterion, it is preferable to use pulse rather than continuous tone. This option is selected through key Nº 6.

1.6.2. DETERMINATION PROCEDURE FOR HEARING THRESHOLD LEVELS THROUGH BONE CONDUCTION WITHOUT MASKING NOISE

The audiometer SIBELMED in its AS5-AO and AS5-AOM versions also permits studying the patient's
bone conduction. The frequencies and levels applicable with this unit are following:

Hz	250	500	1000	2000	3000	4000
Máx. dB	40	50	50	50	50	50
Mín dB	-10	-10	-10	-10	-10	-10

The examination consists of determining the hearing threshold levels when pure tones through bone conduction are provided. For that purpose select letter "B" (Bone) through key Nº 7 in the corresponding digit on the screen. Fig. 1.5.6.

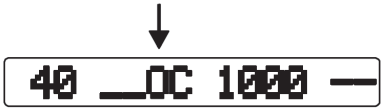


Fig.1.5.6.

The investigation of the threshold of bone conduction is more delicate to carry out and to interpret. For this reason you have to be very careful when carrying it out.

The correct position of the vibrator is very important in order to carry out determinations through the bone conduction. Place it on the mastoid. Apply a tone, a few decibels above the threshold, indicating the patient to move it along the mastoid until the zone where he can hear it loudest. Make sure the vibrator is perfectly coupled to the mastoid and it does not touch the ear, in order to avoid cartilaginous conduction.
In threshold examination through boneconduction without masking the opposite ear should be absolutely free, that is to say, without the earphones on, because their occlusive effect may disturb the test results.

Hearing threshold determination through bone conduction should be carried out as described in section 1.5.1.DETERMINATION PROCEDURE FOR HEARING THRESHOLD LEVELS THROUGH AIR CONDUCTION WITHOUT MASKING NOISE

1.6.3. DETERMINATION PROCEDURE FOR HEARING THRESHOLD LEVELS THROUGH AIR CONDUCTION OR BONE CONDUCTION WITH MASKING NOISE

The SIBELMED AS5-AM audiometer makes possible to study the hearing thresholds of air conduction with masking noise, and the AS5-AOM the thresholds of air and bone conduction with masking noise.

The type of masking noise used by these audiometers is as follows:

- White Noise of Wide Band
- Range from 30 to 80 dB SPL (Sound Pressure Level)
- 5 dB level increases

The earphone presenting the masking signal is the opposite to the one sent by the air conduction.
For example, if the pure tone signal is sent through the right earphone, the masking signal can be sent through the left one, or conversely.

When the exploration is carried out through bone conduction, the masking always turns up though the right earphone.

The masking technique requires skilful handling. It must not interfere with the ear that is being examined while the intended ear is being nullified. Therefore, we leave to the specialist's criterion to decide the following:

- When is masking necessary
- How to determine its initial intensity
- How to determine the threshold of tone with masking.
- etc.

2. TECHNICAL SPECIFICATIONS

2.1. CONFIGURATION ACCORDING TO MODELS

	AS5-A	AS5-AM	AS5-AO	AS5-AOM
AIR CONDUCTION	YES	YES	YES	YES
BONE CONDUCTION	NO	NO	YES	YES
CONTINUOUS TONE	YES	YES	YES	YES
PULSETONE	YES	YES	YES	YES
MASKINGNOISE	NO	YES	NO	YES
TDH39 EARPHONES	YES	YES	YES	YES
B71 or B72 BONE VIBRATOR	NO	NO	YES	YES
SIGNAL INDICATOR	YES	YES	YES	YES
PATIENT'SRESPONSE	YES	YES	YES	YES
LCDSCREEN	YES	YES	YES	YES

2.2. FREQUENCIES AND LEVELS

Frequency, Hz	250	500	1000	2000	3000	4000	6000	8000
Max. Pure Tone AC, dB HTL	90	105	105	105	105	105	90	80
Max. Pure Tone BC, dB HTL	40	50	50	50	50	50	—	—
Min. AC/BC, dB HTL	-10	-10	-10	-10	-10	-10	-10	-10

Level increments	5 dB
Frequencyaccuracy	± 2 %
Levelsaccuracy	± 3 dB
Calibration Regulations	ISO 389, ANSI 3.26-1981

2.3. MASKING NOISE

Type of signal	White noise of wide band
Level range	from 30 to 80 dB SPL
Level increments	5 dB

2.4. TRANSDUCERS

Air conduction	Earphones type TDH 39 (pair)
Bone Conduction	Bone vibrator type B71 or B72

2.5. GENERAL INFORMATION

Functions control	Tactile membrane keyboard
Data presentation	LCD screen
Store temperature	From 0 to 60 ºC
Operating temperature	From 10 to 40 ºC
Relative humidity	less than 85% (no condensation)

Power 220 V, 50 Hz, 15 VA
Size 324 x 246 x 95 mm
Weight 3 Kg approx.

2.6. APPLICABLE STANDARDS

1. Related to the al Product

MEDICAL DEVICE

- 93/42CEE Directive (RD 1591:2009)

ELECTRICAL SAFETY

• EN 60601-1: 2006 Seg. medical equipment: Class type B

EMC

• EN 60601-1-2:2007 EMC in medical equipment (Not vital support). See **APPENDIX 1. ELECTROMAGNETIC COMPATIBILITY**

AUDIOMETERS

• EN 60645-1:2001 Pure tone audiometers
• ANSI S3.6-2004 Specifications for audiometers.
* Only models with speech audiometry option
** Only models with High Frequency option

CALIBRATION

• EN ISO 389-1:2001 Air conduction calibration (supra-aural)
• EN ISO 389-3:1999 Bone conduction calibration
• ANSI S3.6-2004 Specifications for audiometers.

*** Only models with Free field option

USABILITY AND APTITUDE FOR USE

• EN 60601-1-6:2010 General requirements for safety. Part 1-6. Collateral standard: Usability
• EN 62366:2008 Application of engineering skills to use medical devices

VIBRATION AND TEMPERATURE

• Series EN 60721:1995 Classification of environmental conditions
• Series EN 60068:1999 Environmental testing

BIOCOMPATIBILITY

• ISO 10993.1:2009 Biological evaluation of medical devices. Part 1.

SOFTWARE

• EN 62304:2006 Software for Medical Devices

DOCUMENTATION AND INFORMATION

• EN 1041:2008 Information supplied by the manufacturer of medical devices
• EN 15223-1:2012 Graphical symbols for use in labeling in medical devices

2. Related to the manufacturer

QUALITY

• EN ISO 13485:2012 Quality management systems. Requirements for regulatory purposes.
• EN ISO 9001:2008 quality management. Requirements
• EN ISO 14971:2012 Risk management in medical equipment

WASTE

• RD 208/2005 Electrical and electronic equipment and waste management. Transposition of WAEE 2002/96/CE Directive

3. To be satisfied by the user

AUDIOMETRY

• EN ISO 8253-1:1998 Fundamental liminal audiometry of pure tones in air and bone conduction.
• EN ISO 8253-2:1998 Free field audiometry with test signals of pure tones and narrow bands noise
• EN ISO 8253-3:1998 Vocal audiometry
• EN 26189:1991 Tonal liminal audiometry for air conduction hearing preservation.

DATA PROTECTION

• Compliance with LOPD and 95/46/CE Directive

WASTE

• RD 208/2005 Electrical and electronic equipment and waste management. Transposition of WAEE 2002/96/CE Directive

2.7. SIMBOLOGY

SN SERIAL NUMBER

 MANUFACTURER (The date of manufacture, name and address of manufacturer)

 TEMPERATURE LIMITATION

 HUMIDITY LIMITATION

 PREASURE LIMITATION

 APPLICABLE PART B

 CAUTION

 EARTH

 DISPOSAL OF ELECTRICAL OR ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

2.8. USEFUL LIFE

7 years

3. FUNCTIONAL DESCRIPTION

The audiometer, as it is well known, consists of the following parts:

- Low frequency oscillator
- Attenuator for tone level control
- Air conduction earphones and bone vibrator (if it has one)
- Switch for sending at will generated sound

Next, a more detailed description of the audiometer SIBELMED AS5 is provided. See Block Diagram.

3.1. GENERATOR AND TONES CONTROL

3.1.1. TONES GENERATOR AND FREQUENCIES SELECTOR

The tones generator comprised in this audiometer is a sine Wien bridge oscillator. It uses an operational amplifier selfrregulated in amplitude by a field effect transistor FET.

Frequencies generated by this oscillator are 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz. They are selected through the keyboard through an electronic conmutator controlled by the processor.

The tones generator output is applied to an adjustment stage. Each frequency is calibrated at the manufature process or at every periodical check-up by means of an artificial ear for the air conduction earphones and an artificial mastoid for the bone vibrator. These calibration levels are carried out in dB HTL (Hearing Threshold Level), according to regulations.

3.1.2. ATTENUATOR AND dB TONES SELECTOR

Once calibrated,the tone signal goes through five attenuation stages of 5, 10, 20, 40 and 40 dB. They provide a control in 5dB jumps, from -10 up to 105 dB.

The stage selection is carried out through the processor by means of electronic conmutators.

3.1.3. SEÑAL/SIGNAL KEY

The output of the last stage of the attenuator is connected to a silencer circuit. This, by means of LDR photoelectric cells, blocks the way of the tone signal whenever the "SEÑAL/SIGNAL" key is not pressed down. The grade of attenuation of this system is superior to 80 dB. On pressing the "SEÑAL/ SIGNAL" key this circuit is defused and the tone freely moves on to the function selector.

3.2. MASKING NOISE

The masking noise is white noise wide band type. This is generated from an aleatory sequence of rectangular pulses that covers the audible tone spectrum.

This signal is controlled by the processor, both for generation and for processor attenuator control.

The masking signal attenuator consists of four attenuation stages of 5, 10, 20, and 20 dB. With them, masking levels between 30 and 80 dB are selected.

Once the signal has been shaped and calibrated, apply the function selector.

3.3. FUNCTION SELECTOR AND CONDUCTION PATHS

3.3.1. FUNCTION SELECTOR

Pure tone and masking noise should be applied at the inputs of an electronic conmuter controlled by the processor. The mission of this device is to send each one of these signals to the

corresponding paths that have been previously selected by the keyboard.

The electronic conmuter output can send the pure tone signal to the right earphone, to the left earphone or to the bone vibrator, and the masking noise either to the right or left earphone.

3.3.2. CONDUCTION PATHS

The SIBELMED AS5 audiometer, as it has been said before, has Air Conduction and Bone Conduction (optional).

Three power amplifiers feed the right, left earphones and bone vibrator.

3.4. PROCESSOR

The processor consists of a set of electronic devices that store, conduct, receive and send out information. In outline, it has the following parts:

- ROM resident control program (of 8Kb, 1Kb = 1000 bytes)
- RAM memory (of 2Kb)
- Central Process Unit CPU
- Comunication Controls

3.4.1. PROGRAM

It is in charge of conducting all the orders sent to it from the keyboard so as to carry out the audiometric examination correctly.

The control program is utterly developed in assembling language, assuring by that a high control speed.

The memory where the program is recorded is ROM type (Read Only Memory).

3.4.2. RAM MEMORY

The data storage capacity is of 2 Kb. A RAM memory is used (Random Access Memory) in order to keep the data and stage

where the audiometer is.

3.4.3. C.P.U.

It is the device that conducts and carries out instruction comprised in the program. MOS 6502 technology is used with a clock frequency of MHz

3.4.4. CONTROLLERS

They are in charge of the data exchange between the keyboard, screen, patient warning and selector on the one hand, and CPU on the other.

3.5. PATIENT RESPONSE, KEYBOARD AND SCREEN

El SIBELMED AS5 audiometer has a circuit driven by a push-button for the patient to give warning when he hears the applied tones. This system has been developed in such a way that it makes possible for the operator to detect whether the patient is sending a false warning.

The operator controls the audiometer through a nine-key tactile membrane keyboard. This system is silent, reliable and easy to handle. In this way noises coming from rotary conmuters, both mechanical and electrical are avoided.

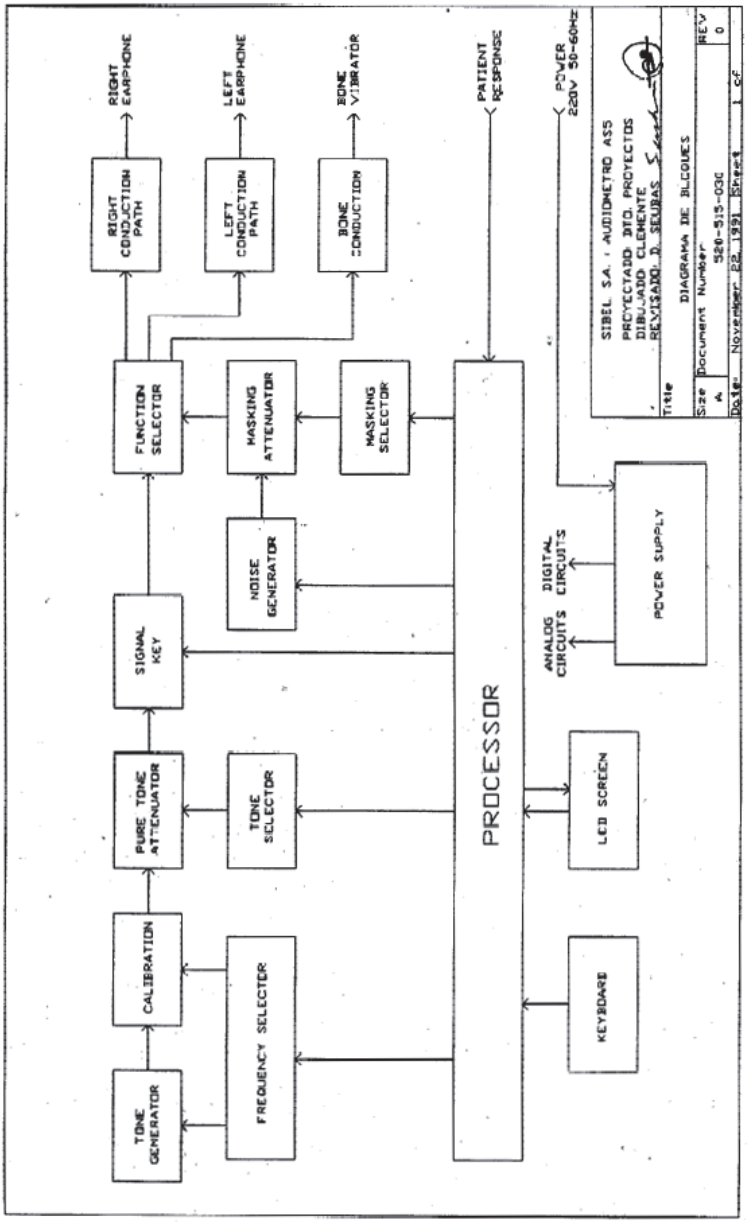
The audiometer operating state all the time is displayed on the LCD liquid crystal screen. This makes possible a clear and quick view of levels, frequency, path, etc. that are being applied or are to be applied to the patient. The screen has 16 large and distinctive alphanumerical digits.

3.6. POWER SUPPLY

As the audiometer is an electronic unit, it requires an electric source to operate. This is taken from a 220V 50Hz network (other voltages or / and frequencies are available). In order to guarantee the safety of patient, operator and their environment, the network voltage is applied to a transformer in a highly isolated fashion. The output is of very low tension and it feeds the

whole system.

The voltage provided by the transformer goes through filtering and stabilization circuits. These prevent the audiometer operation fom being afected by possible flutters in the supply network.


RIGHT EARPHONE
LEFT EARPHONE
BONE VIBRATOR
PATIENT RESPONSE
POWER 220V 50-60Hz
RIGHT CONDUCTION PATH
LEFT CONDUCTION PATH
BONE CONDUCTION
FUNCTION SELECTOR
MASKING ATTENUATOR
MASKING SELECTOR
NOISE GENERATOR
SIGNAL KEY
PURE TONE ATTENUATOR
TONE SELECTOR
CALIBRATION
FREQUENCY SELECTER
TONE GENERATOR
PROCESSOR
ANALOG CIRCUITS
DIGITAL CIRCUITS
LCD SCREEN
KEYBOARD
POWER SUPPLY
SIBEL S.A. : AUDIOMETRO AS5
PROYECTADO DTO. PROYECTOS
DIBUJADO CLEMENTE
REVISADO D. SELVAS
Title
DIAGRAMA DE BLOQUES
Size
A4
Document Number
520-515-000
REV
0
Date: November 22, 1991 Sheet 1 of

4. AUDIOMETRIC TECHNIQUE

The audiometric technique is so wide due to the high number of modalities that exist. To do a description of each one would be a complex task and it doesn´t the purpose of this manual.

Therefore, for those specialist that want a complementary information, they can consult the different bibliographies that are published about this topic.

5. PRESERVATION

The AS-5 audiometer requires, as every equipment and specially due to its medical application, a preservation or maintenance, first pointed to the sefety of the patient, operator and environment; second to insure the reability and accuracy of the functions which it has been developed for. Therefore, a serie of routines must be performed:

5.1. PRESERVATION

Preservation is the action directed to maintain the equipment in a correct operating condition. The person that has to perform it doesn´t need any special technical skill, except the proper knowledge of the functions and manipulation of the equipment. It can be performed by the same user. The operations to be carried out are described below:

5.1.1. CLEANING THE AUDIOMETER

The audiometer can be wiped smoothly with a dry or sligthly water-moistened cloth and then dried. You must pay attention to no liquid go into the audiometer or its connectors.

Don´t use abrasive or solvent substances.

5.1.2. CLEANING THE ACCESORIES

The cleaning method described before is also applied to the accesories.

In the case of the air-way headphone cushions, they can be cleaned better if they are put out the headphone and washed with water and soap, and dried perfectly before mounting in the headphone.

WARNING
The bone-way vibrator is a fragile device. Little hits can break it. So it is recommended to handle with care.

5.2. PREVENTIVE MAINTENANCE

The preventive maintenance consist on all those technical actions that keep the equipment in a good condition.

Some different actions can be performed but standart rules like ISO 8253-1 are suggested. Sibel suggests at least to follow the next procedures:

5.2.1. ROUTINE-CHECKUP AND SUBJECTIVE TESTS

This routine-checkup will be performed once per week.

1st. Verify all the connections are connected and all the cables and connectors are in good condition.

2nd Check subjectively that the audiometer air-way and bone-way output are equal in bothchannels and in all frequencies. To do this, apply a level of 10 or 15 dB, just it can be heard. (Of course, the person that performs the test should have a good hearing.)

3rd Check with a level of 60 dB in air-way and 40 dB in bone-way that no distortion nor noise nor parasitic signal can be heard testing at all frequencies.

4th Check that the signal key turns on-off properly.

5th Check that the atenuator levels performs their function without noise or interferences.

6th Check that the headphone and vibrator strips are correct.

5.2.2. OBJECTIVE CHECKUP

This checkup consists on a general and technical verification of the safety, adjustment, functions, calibrations that configure the device.

The calibration is made with artificial mastoid and ear according to the standards that are applied to.

THIS CHECKUP MUST BE MADE ANNUALLY and following the Verification and Adjustment procedure of the SIBELMED AS5 owned by the manufacturer. This kind of operations should be made by qualified technical personnel of the maintenance department of the center, supplier or manufacturer.

In any case, SIBEL S.A. as manufacturer, must authorize and allow by writing, at least during the warranty period, to the technical service to perform this maintenace. In any case SIBEL S.A. will not admit any responsability for any damage, misfunction, etc., which might result from a defective maintenance by people not working directly in SIBEL S.A.

5.3. CORRECTIVE MAINTENANCE

The corrective maintenance consist on fixing the equipment which it has been put out of service for bad operation or bad use.

In case of detecting a system break-down which it does not permit a normal use, disconnect the equipment from the mains power and contact the correspondent technical service, specifiying as detailed as possible the anomaly detected.

If the equipment needs a corrective maintenance, it will be convenient also to perform the preventive maintenance described in the paragraph 5.2.2 OBJECTIVE CHECKUP.

This requirement must be specified to the technical service that fix the equipment since possible misfunctions can produce disadjustments not easily to find without a checkup and calibration.

Guidance and manufacturer's declaration – electromagnetic emissions		
AS-5 AUDIOMETER is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1 Class B	AS-5 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Conducted) emissions CISPR 11 (EN 55011)	Group 1 Clase B	AS-5 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions EN-IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-2	Yes	

Guidance and manufacturer's declaration – electromagnetic immunity			
AS-5 AUDIOMETER is intended for use in the electromagnetic environment specified below. The costumer or the user of AS-5 should assure that it is used in such an environment.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst EN-IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±1 kV differential ±2 kV common mode	±1 kV differential ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	<5 % Ut (>95 % dip inUt) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AS-5 requires continued operation during power mains interruptions, it is recommended that the AS-5 be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	3 A/m	3 A/m	El campo magnético en la sala debe ser suficientemente bajo para asegurar la realización del test.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

AS-5 AUDIOMETER is intended for use in the electromagnetic environment specified below.
The costumer or the user of AS-5 should assure that it is used in such an environment.

Immunity test	EN-IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
RF conducida EN-IEC 61000-4-6	3 Vrms 150KHz a 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of AS-5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{E}\right]\sqrt{P}$ de 80 MHZ a 800 MHZ
RF radiada EN-IEC 61000-4-3	3 Vrms 80 MHz a 800 MHz	3 V/m	$d=\left[\frac{3.5}{E}\right]\sqrt{P}$ de 80 MHZ a 800 MHZ $d=\left[\frac{7}{E}\right]\sqrt{P}$ de 80 MHZ a 800 MHZ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1. At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which AS-5 is used exceeds the applicable RF compliance level above, AS-5 should be observed to verify normal operation

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and AS-5 AUDIOMETER

AS-5 AUDIOMETER is intended for use in an electronic environment in which radiated RF disturbances are controlled. The costumer or the user of AS-5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and AS-5 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	From 150 kHz to 80 MHz $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	**From 80 MHz to 800 MHz** $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	**From 800 MHz to 2.5 GHz** $d=\left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 800 MHz, the separation distance for the higher frequency applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absortion and reflection from structures, objects and people.